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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,289	07/11/2001	Peter A. Burke	3056	8411

7590

01/28/2004

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EXAMINER
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KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/903,289

### Applicant(s)

BURKE ET AL.

### Examiner

Ganapathy Krishnan

### Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

Art Unit: 1623

### **DETAILED ACTION**

The amendment file October 31, 2003 has been received entered in to the record and carefully considered. The following information provided affects the instant application as follows:

1. Claims 1-10 have been cancelled.

Claims 11 and 12 are pending.

In the office action mailed July 7, 2003 claims 11 and 12 were indicated as allowable. The allowability of claims 11 and 12 is withdrawn and the following rejections are made of record.

#### ***Joint Inventors***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsen (US 5958461) in combination with Ueno et al (US 4869270) and Stoner (US 4925033).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 12 are drawn to a package containing a condom and a spermicidal and a microbicidal composition comprising specific percentages of nonoxynol-9, polyacrylic acid and hyaluronic acid and having a pH of about 5.

Larsen teaches a gelled vaginal composition in the form of a gel, which comprises an acrylic acid modified polymer, an active spermicidal agent and a buffer to maintain the pH of the composition between 3 and 5. The spermicidal agent in Larsen's composition is nonoxynol-9. The composition comprises 1.0 to about 3.0% of the acrylic acid polymer and specifically the pH is between 3.4 to 5.5 (col. 10, lines 13-55; col. 8 examples 2-4). 1% nonoxynol-9 is used in the

Art Unit: 1623

composition (examples 2-4, col. 8). However, Larsen does not teach a composition comprising hyaluronic acid and a lubricating base and a condom in a package.

Ueno et al teach the use of an aqueous solution of the polysaccharide hyaluronic acid with lubricants for applying to the surface of a condom (col. 1, line 55 through col. 2, line 5 and example 4 in col. 3). The composition in example 4 has 1% hyaluronic acid. Ueno et al also disclose that other soluble materials like glycerin, glycols and polyglycols as wetting materials (col. 2, lines 55-60) which one of ordinary skill in the art will realize also can act as lubricants. According to Ueno (col. 1, lines 43-50) the polysaccharide in their composition also serve as lubricants. However, Ueno et al do not teach a composition comprising nonoxynol-9 and polyacrylic acid at a pH of about 5.

Stoner drawn to microbicidal cleansers discloses that spermicide compounds such as nonxynol-9 can also act as anti-microbial agents (col. 1, lines 53-59).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art teachings above to make a package containing a condom and a spermicidal and microbicidal composition as instantly claimed since the active agents and their percentages are seen to be disclosed.

One of ordinary skill in the art would be motivated to do so since combining the composition of Larsen and Ueno to include hyaluronic acid would give a composition that would have a wide spectrum of antimicrobial activity which prevents not only pregnancy and sexually transmitted diseases during sexual encounter but also maintain and enhances the protective function of the vaginal flora (Larsen, col. 3, lines 5-12). Moreover, according to Ueno

Art Unit: 1623

The coating of such a composition on the outside of the condom will have a direct protective effect on the vaginal cavity of the female (Ueno, col. 3, lines 10-19).

***Conclusion***

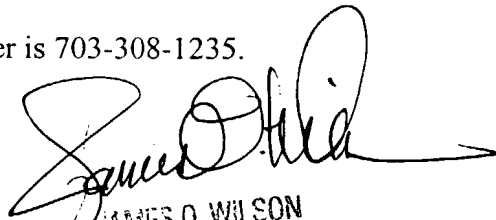
1. Claims 11 and 12 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK

  
JAMES O. WILSON  
SUPERVISOR/INVENT EXAMINER  
TECHNOLOGY CENTER 1600